

Specification Amendments

Please substitute the following paragraphs for the like numbered paragraphs of record:

[0002] The use of a metal tube for medical devices of the type considered herein is known. Since these devices must be capable of being introduced into a body through natural ducts up to the part to be treated, the tube used therein, at least in its forward or distal portion, must exhibit suitable flexibility to follow ~~even~~ the turns of these ducts without damaging them.

[0003] Systems for ~~flexibilising~~ rendering a stiff metal tube flexible have already been proposed, but they have been found capable of being improved ~~anyway~~ further.

[0004] The present finding therefore aims at proposing a metal tube obtained by an innovative method for ~~flexibilising~~ rendering it flexible, which is simple, easy and inexpensive to be realised.

[0006] Another object of the invention is that of obtaining ~~that the~~ variation of flexibility ~~is such as~~ to allow a gradual passage between the ~~non-flexibilised~~ non-flexible portion of tube and the front portion or distal end so that the latter is very flexible.

~~[0008] Such object is obtained by a tube according to claim 1.~~

[0011] Fig. I shows a three-dimensional view of a piece of tube with a ~~flexibilised~~ more flexible portion according to an embodiment;

[0015] Fig. 5 shows a ~~transversal~~ cross section in the direction of arrows A A on Fig.3;

[0016] Figs. 6 and 7 show ~~two more transversal~~ cross sections respectively according to arrows B B and N N on Fig. 4;

[0025] The tube proposed herein exhibits a wall 11 and, in a distal area 12, at least one portion 13 of its length which is ~~flexibilised~~ rendered more flexible as compared to the tube's ~~own~~ normal stiffness.

[0026] According to an embodiment, the ~~flexibilised~~ more flexible portion 13 extends for a length comprised between 70mm and 110mm, preferably between 80mm and 100mm, measured starting from the distal end.

[0027] ~~For its flexibilisation~~ To render it more flexible, in the wall of such portion 13 of the starting tube there are obtained notches 14. The term "notch" means both a thorough slit that at least in one portion passes through the entire thickness of the tube wall, and a groove that in no portion passes through the entire thickness of the tube wall.

[0029] ~~If an even~~ continuous flexibility is required along the entire ~~flexibilised~~ portion 13, notches 14 for example are all the same by size and depth, and step P of their helical pattern is constant (Fig. 8).

[0030] However, to better satisfy the convenience of use and the performance of the tube used in a catheter, the flexibility of the ~~flexibilised~~ portion 13 preferably is variable, to be higher in the vicinity of the distal end and decrease in the opposed direction.

[0031] According to an embodiment, a notch exhibits, at least for some portions of it, a prevailing longitudinal extension that determines a notch direction.

[0032] The flexibility of portion 13 can therefore be selected and realised in various manners. For example, it is possible to vary the inclination angle α of notches 14 between ~~said~~ the notch direction and a circumference obtained on the outside surface of the tube and/or increase step P.

[0034] Similarly, the flexibility along the ~~flexibilised~~ portion 13 can be ~~diversified~~ varied by varying the width A of notches 14, also in this case by reducing it starting from the zone close to the distal end. The width A of the notches ~~can~~ can be varied starting from a minimum (Fig. 15a) which is equal, for example, to the useful width of the cutting tool. According to a preferred embodiment, the minimum notch width is the typical width of a cut obtained by laser technology. Such minimum width therefore is comprised between about 5 μm and about 30 μm , preferably between about 10 μm and about 25 μm .

[0035] A larger width A can be obtained by a rectangular notch such as that shown in figure i5b or with a parallelogram notch. A similar notch imparts higher deformability (both ~~flexional~~ radial and axial) to the tube and reduces the over-tension or stress concentration effect that typically generates around the apices of a notch. The width of such notch can be as much as about 1 mm.

[0036] It is also possible, in order to reduce the stress concentration effect around the notch apex without having to increase the tube deformability, to use a cut geometry such as that shown in figure 15c, wherein the width A of the notch is determined on the basis of the flexibility needs of ~~flexibilising~~ the tube, whereas the notch apices' ~~over-tensions~~ stress concentrations are relieved by circular holes whose diameter D is larger than the width A of the notch.

[0037] According to a further embodiment, the flexibility along the ~~flexibilised~~ portion 13 can be ~~diversified~~ varied by thinning out notches 14 starting from the zone close to the distal end. As an alternative, a variable flexibility at the ~~flexibilised~~ portion 13 can be obtained by applying a combination of two or more of the above systems, with reference to the shape, to the arrangement and pattern of notches 14 in the tube wall.

[0038] Reference shall be made below to the figures from 8 to 11, which show the plane developments of the cylindrical outside surfaces of the ~~flexibilised~~ portions 13 of the tube according to some embodiments.

[0040] Figure 9 shows the plane development of the outside tube surface according to another embodiment. According to such embodiment, notches 14 are arranged with null inclination α . In other words, the notches are perpendicular to the tube axis. The notches, for example, exhibit a width E of about 240° and a phase displacement F of about 120° . The An expert of the art will promptly understand that in this embodiment it is not possible to keep the definition given above of "start" and "end" of the notch, since both ends are located at the same axial distance from the distal end. The expert of the art will also clearly see that in any case that it is possible to arbitrarily identify, in each notch, an end as start and the other end as end of the same notch.

[0041] According to a further embodiment, the axial distance between two consecutive notches starts from a value B and increases every time, for example by an amount C. Since proceeding from the distal end in a proximal direction the axial distance between the notches increases continuously, a very gradual passage is obtained in this embodiment from the flexibility of the non-machined tube to the distal end, which is the most ~~flexibilised~~ flexible.

[0045] Starting from the distal end in proximal direction, the notches have an increasing length but their projection in terms of degrees on an outside circumference of the tube is constant. For example, the notches exhibit a width E of 240° and a phase displacement F of 300° . These special values allow obtaining a very even flexibility as the radial stressing direction varies. Moreover, this particular embodiment allows for obtaining, for the deformed tube, a very regular profile whose curvature varies continuously.

[0046] In the embodiments shown in figures 10 and 11 it is possible to define an axial distance between consecutive notches. ~~So is defined~~ Such defines the distance that separates the projections of the respective starts of the notches on the axis or on a generatrix of the tube cylindrical surface. Note that also in these embodiments the axial distance between two consecutive notches increases from the distal end of the tube in proximal direction.

[0047] The ~~flexibilised~~ tube according to the invention can be realised with metal materials, preferably with stainless steel, with polymeric materials or with composite materials.

[0049] The fact that the tube is ~~flexibilised~~ rendered flexible by a plurality of different and separate notches ensures a great residual resistance of the tube, along with an optimum flexibility.

[0050] Several changes, adaptations and replacements of elements with functionally equivalent ones can be made by ~~a man~~ one skilled in the art to the preferred embodiments described above without departing from the scope of the following claims.